

**REMARKS**

Concurrently filed herewith is a Petition to Withdraw Finality.

Entry of this Amendment is proper under 37 C.F.R. §1.116, since no new claims or issues are raised and the new rejection based on Walker requires that the Examiner respond on the record prior to appeal in order to clarify issues for appeal. As pointed out herein, this new rejection fails to meet the Examiner's initial burden.

It is noted that, notwithstanding any claim amendments made herein, Applicant's intent is to encompass equivalents of all claim elements, even if amended herein or later during prosecution.

Claims 1-21 are pending in the present Application. Claims 1, 2, 10-19, and 21 stand rejected under 35 USC §103(a) as unpatentable over US Patent 4,936,862 to Walker, further in view of US Patent 6,540,707 to Stark et al., further in view of US Patent 5,050,618 to Larsen. Claims 3-5 stand rejected under 35 USC §103(a) as unpatentable over Walker/Stark/ Larsen, further in view of Applicant's Admitted Prior Art. Claims 6, 7, and 20 stand rejected under 35 USC §103(a) as unpatentable over Walker/Stark/ Larsen, further in view of US Patent Publication 2002/0072828 to Turner et al. Claims 8 and 9 stand rejected under 35 USC §103(a) as unpatentable over Walker/Stark/Larsen/Turner, further in view of Applicant's Admitted Prior Art.

The prior art rejections based on Walker are respectfully traversed in view of the following discussion.

**I. THE CLAIMED INVENTION**

As described and claimed, for example by claim 1, the present invention is directed to a computerized method of at least one of designing, constructing, and adjusting an orthodic, as follows.

Pressure and acceleration sensors are provided. The sensors are mounted in a joint-enclosing device. The data produced by the sensors during actual operation of the joint-enclosing device worn by a specific individual is transmitted.

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A computer receives the sensor signals for analysis. A stress-and-acceleration map is created, based on the sensor-based data and this stress-and-acceleration map is used to create a virtual orthodic model.

The advantage of the present invention is that an optimal model can be derived from the dynamic pressure and acceleration sensor data. The conventional method of designing and constructing orthodics were constrained by static fitting techniques alone.

## II. THE PRIOR ART REJECTIONS

The Examiner alleges that US Patent 4,936,862 to Walker, further in view of US Patent 6,540,707 to Stark et al., further in view of US Patent 5,050,618 to Larsen, renders obvious the present invention, as defined by claims 1, 2, 10-19, and 21, and that this combination of references, when further combined by US Patent Publication 2002/0072828 to Turner et al. renders obvious claims 6, 7, and 20.

The Examiner further alleges that Walker/Stark/ Larsen, further in view of Applicant's Admitted Prior Art, renders obvious claims 3-5 and that Walker/Stark/Larsen/Turner, further in view of Applicant's Admitted Prior Art, renders obvious claims 8 and 9.

Applicants submit that the rejection currently of record fails to meet the burden of a *prima facie* rejection under 35 USC §103(a) for the following reasons.

The Examiner concedes that Walker fails to provide pressure and acceleration sensors or mounting such sensors on a joint-enclosing device to generate a stress-and-acceleration map. To overcome this conceded deficiency in Walker, the Examiner relies upon Stark for teaching the use of a joint-enclosing device having pressure and acceleration sensing capability and providing sensor data into a microprocessor and upon Larsen for teaching stress-strain loop at extremes of the range of motion of a joint.

The Examiner further states that one of ordinary skill in the art would have been motivated to modify Walker with Stark: "... because it would provide for collecting information in support of a hinge joint or at least one vertebra" and to modify Walker with Larsen: "... because it would provide for analyzing and evaluating the elastic component of joint stiffness to create the orthodic model based on the stress-stain loop".

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Applicant first points out that the rejection currently of record merely engages in a circular argument. That is, the motivation to modify/combine references merely asserts that one of ordinary skill in the art would have been motivated to modify Walker with, for example, Stark in order to achieve the benefit of having made the modification.

Using this circular argument, everything becomes obvious, since it can always be asserted that one would be motivated to modify existing art in order to obtain the benefit of having made the modification.

As pointed out in MPEP §211.02: *"In determining the differences between the prior art and the claims, the question under 35 U.S.C.103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious"* (emphasis in MPEP itself).

This guideline reflects the well established concept in patentability evaluation that a new invention may "merely" be a new and different combination of known elements.

Second, it is pointed out that MPEP §2143.01 clearly states a second guideline: *"The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination"* (emphasis in MPEP itself).

Along these lines, Judge Rader wrote in the recent Federal Circuit Court of Appeals holding in *Ruiz v. A.B. Chance Co.*, Federal Cir., No. 03-1333, January 29, 2004:

*"In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. *Env'tl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result - often the very definition of invention."*

Although the holding in that case left undisturbed, under the "clear error" standard of review by an appellant court, the conclusion of the District Court that the prior art references

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were properly combinable, it specifically explained that it declined to reverse this conclusion because "... *the two references address precisely the same problem ...*" (emphasis by Applicant).

This aspect of the *Ruiz* holding, in which precisely the same problem is being addressed by both references, is not present in the Walker/Stark/Larsen/Turner references used in the prior art evaluation of the present Application. That is, in Walker, the problem addressed is that of construction of a bone prosthesis to replace one or both bones in a joint, a problem inherently different from that addressed by Stark in which a portable orthopedic restraining device that is external to the joint is used to provide a "passive correction of biological deformity and/or the exercising of muscles and other tissues associated with a joint ...."

Third, Applicant points out that the technique in Walker is based on simply determining the difference of a specific patient's bone dimension with that of an "average anatomical three-dimensional shape of the bone. This method is entirely different from the use of pressure/acceleration sensors of either Stark (or the present invention) in which sensors are mounted on a frame device external to the joint or of the technique.

Therefore, Applicant additionally submits that Walker cannot serve as the primary reference for Stark under the following guideline in MPEP §2143.01: "*The proposed modification cannot change the principle of operation of a reference*".

Finally, as previously pointed out in the previous Amendment filed October 9, 2003, even if all the cited reference were to be combined, the result would not provide a stress-and-acceleration map, as one of ordinary skill in the art would understand this term. Although the Examiner is expected to give the "broadest reasonable interpretation" to claim language, this interpretation is constrained, since, as explained in MPEP §2111: "*The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.*"

That is, Applicant submits that one of ordinary skill in the art would not at all consider the "strain signal as a function of angular position" (see line 7 of column 3 of Larsen) as meaning a "stress-and-acceleration map" of a joint.

Therefore, even if Larsen were to be incorporated into Walker, the resultant combination would still not provide the invention defined by the independent claims.

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The Examiner relies upon Applicant's Admitted Prior Art as demonstrating that interpolation techniques were known and upon Turner as demonstrating non-linear techniques. Even if these two secondary references were considered as being properly combinable with Walker, these references do not overcome the basic deficiencies identified above.

Hence, turning to the clear language of the claims, there is no teaching or suggestion in Walker of "... [a] computerized method of at least one of designing, constructing, and adjusting an orthodic, said method comprising: mounting pressure and acceleration sensors in a joint-enclosing device; transmitting the data produced by said sensors during actual operation of said joint-enclosing device worn by a specific individual; receiving said sensor signals for analysis by a computer; creating a stress-and-acceleration map based on said sensor-based data; and creating a virtual orthodic (model) for support and comfort based on said stress-and-acceleration map", as required by claim 1. A similar argument applies to independent claims 11, 14, and 21.

Relative to the rejection for claim 2, it is again noted that the Examiner's characterization of lines 49-57 of column 2 of Stark is incorrect. That is, there is no suggestion whatsoever to use "temperature, moisture, and skin conductivity sensors". Applicant submits that one of ordinary skill in the art would not consider the description: "*Bladders spread the forces ... injury to the skin*" as reasonably suggesting the use of a temperature, moisture, or skin conductivity sensor.

Moreover, relative to the rejection for claim 9, Applicants can find no reference in the Applicant's Admitted Prior Art discussion on Page 1 of the present Application to either expert systems or fuzzy logic techniques. The discussion at the bottom of Page 5 of the specification is not a part of the Applicant's Admitted Prior Art and cannot be characterized by the Examiner as such.

Therefore, the rejection for claims 3-5, 8, and 9 are likewise improperly based upon the characterization that Page 5 of the specification is Applicant's Admitted Prior Art.

For the reasons stated above, the claimed invention is fully patentable over the cited references.

Further, the other prior art of record has been reviewed, but it too, even in combination with Walker, Stark, Larsen, or Turner, fails to teach or suggest the claimed invention.

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### III. FORMAL MATTERS AND CONCLUSION

In view of the foregoing, Applicant submits that claims 1-21, all the claims presently pending in the application, are patentably distinct over the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

The Commissioner is hereby authorized to charge any deficiency in fees or to credit any overpayment in fees to Assignee's Deposit Account No. 50-0510.

Respectfully Submitted,

Date: 3/1/04



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### CERTIFICATION OF TRANSMISSION

I certify that I transmitted via facsimile to (703) 872-9306 this Amendment under 37 CFR §1.116 to Examiner T. Pham on March 1, 2004.



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